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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,928	11/28/2000	Stephen P.A. Fodor	018547036750	9541
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TOWNSEND AND TOWNSEND AND CREW LLP TWO EMBARCADERO CENTER 8TH FLOOR SAN FRANCISCO, CA 94111-3834				
			EXAMINER MARSCHEL, ARDIN H	
			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,928

Applicant(s)

FODOR ET AL.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-155 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-155 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Reconsideration of the instant application has revealed that significant new issues need to be addressed supporting new grounds of rejection. Therefore, applicants are hereby informed that the finality of the Office Action, mailed 7/9/03, is hereby withdrawn, due to newly applied rejections as summarized below.

The amendment, filed 9/8/03, has been entered.

Applicants' arguments, filed 9/8/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **WITHDRAWAL OF ONE OF THE SPECIE ELECTION REQUIREMENTS**

Regarding the scanning practice per se of the instant claims, the specie election which limited examination to claim embodiments wherein the array or holder thereof is moved for scanning is hereby withdrawn. Examination therefore has proceeded to include scanning wherein the either the scanner and/or the array or holder is moved to effect scanning of the substrate surface. The other specie election requirement directed to limiting examination to claim practice wherein target molecules in a sample are already applied to the polymer array of the claims is maintained.

### **SEQUENCE RULE NON-COMPLIANCE**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR

§§1.821(a)(1) and (a)(2). See, for example, peptide sequences disclosed in the specification on page 32, line 26; page 33, lines 30-32; and page 34, lines 8-9.

However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 because it lacks SEQ ID Nos cited along with each of these sequences in the specification. If a new submission of a computer readable form sequence listing is required, applicants are reminded of the additional requirements of 37 CFR §§ 1.821 through 1.825 including a, a paper copy of the sequence listing for the specification and statements under 37 CFR §§ 1.821(f) and (g). Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

#### **NEW MATTER**

Claims 57-155 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Reconsideration of the instant application as originally filed has revealed NEW MATTER in the presently pending claims that is newly identified. The NEW MATTER limitations which are present in all of the presently pending independent claims are

directed either to "computer executable instructions", "computer program code", or "machine instructions", or "executable instructions". These limitations are cited in the instant claims as being either as comprising a "computer readable medium", "computer software product", or "system...comprising...a processor; and a memory". These limitations therefore are reasonably interpreted as being directed to specific computerization practices. Consideration firstly of the instant claims, abstract, and drawings; as originally filed; has revealed only a generic unspecified computer shown in Figures 4, 11, and 13, and related BRIEF DESCRIPTIONs; what may be a computer flow chart, although not labeled as such, in Figures 5A and 5B, and related BRIEF DESCRIPTIONs; and what may be a computer organization, again not labeled as such, in Figure 12 and related BRIEF DESCRIPTION; but without any disclosure of the above listed specific NEW MATTER limitations. That is, there is no disclosure of "executable" instructions, "machine" instructions, or "program code" per se. Consideration of the instant specification, as filed, also reveals a lack of disclosure of the above described NEW MATTER. It is noted that a "programmed digital computer" is cited on page 2, line 16, but is directed to the "flow of liquids from the reactor system" and not any of the presently pending claim practices. The bridging paragraph between pages 3 and 4 of the specification as filed summarizes data collection equipment and practices but none of the above NEW MATTER limitations. The next computerization disclosures are in the specification on pages 53 et seq. in the section entitled "Data Collection". A computer is cited on page 55, lines 1-3 for control of device and data collection but without specifying any written description of executable instructions etc. as listed above

as being NEW MATTER. It may be obvious that a computer such as an IBM-AT as cited on page 55, line 1, operates via executable instructions but that obviousness is an insufficient basis to provide written description. Also the citation of a computer lacks any written description of invention by applicants of executable instructions etc. per se as listed above as NEW MATTER now cited in presently pending claims. On page 55, line 14, a counting program is cited, but without disclosing program code, executable instructions, etc. per se. In the specification on page 57, lines 1-4, an image file, a computer representation, and a computer file is cited but again without written description of the above NEW MATTER limitations. Further data analysis details are described on page 57, lines 5-27, but without any written description that discloses the invention of the above listed NEW MATTER limitations. It is noted that Appendix A is cited in the specification on page 20, line 37, but is cited regarding only array synthesis practice. Claims which depend directly or indirectly from said independent claims also contain this NEW MATTER due to their dependence.

In instant independent claims 65, 86, and 120; last line of each claim; the citation of a "computer readable medium for storing the codes" is NEW MATTER because no written description of a medium for storing codes has been found as filed. Claims which depend directly or indirectly from said independent claims also contain this NEW MATTER due to their dependence.

In instant independent claims 73, 94, 102, and 144; the citations of a scanner comprising a "processor", "a memory coupled to the processor", "memory storing a plurality of machine instructions" that additionally cause the performance of a "plurality

of logical steps" and which are "implemented by the processor" are NEW MATTER because no written description of such specific computer components has been found as filed. Claims which depend directly or indirectly from said independent claims also contain this NEW MATTER due to their dependence.

Instant claim 57, for example, cites the generation of an "average intensity for a given localized area" in the last 2 lines therein. There is no fluorescence intensity limitation as to the data source for said intensity in claim 57. The closest disclosure as filed for average intensity determination is in the specification on page 56, lines 24-28, where an "average of fluorescent intensity" is cited but not without the "fluorescent" limitation. Thus, instant claim 57, being generic as to intensity data type, contains NEW MATTER due to being broader than the average intensity disclosure as filed. This broader unlimited intensity data limitation in claim 57 therefore contains NEW MATTER due to being broader than such a determination as filed. This NEW MATTER is also present in independent claims 65, 73, 78, 86, 94, 102, 108, 120, 132, 144, and claim 57 and claims which depend directly or indirectly from said independent claims due to their dependence, except for claims limited to intensity data being produce from fluorescence such as in instant claim 153, for example.

The NEW MATTER rejection based on a lack of written description as filed regarding instant claims 102-107 containing the limitation of the "less than  $\frac{1}{2}$ " collection of intensity data is maintained and reiterated from the previous office action, mailed 7/9/03. Applicants argue that written support for this limitation is present in the specification on page 56, lines 10-14. Consideration of said page 56 citation reveals

that the written disclosure therein is directed to a specific exemplified fluorescence intensity evaluation and is not described as a generic data collecting practice as in the instant claims which are not limited to fluorescence data collection. This argument therefore is non-persuasive.

### **VAGUENESS AND INDEFINITENESS**

Claims 57-155 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained and reiterated from the previous office action, mailed 7/9/03, regarding the unclarity of instant claim embodiments being limited to polymer array scanning versus a generic scanner of a substrate surface area. The instant amended claims, for example, claim 57, still merely set forth the scanning of an area of a substrate, receiving and collecting pixel data and generating an average intensity over a given localized area thereon. The computer executable instructions per se do not require the presence of any particular material on localized areas of the substrate even though the claim recites the presence of a plurality of polymers, the scanning and averaging per se lacks any particularity regarding said polymers. Whatever average intensity is generated is determined broadly by whatever the scanner is scanning since the instructions per se do not require any particular substrate material presence.

Applicants argue that language for amending the claims was suggested during the Examiner Interview of April 11, 2003. The claim amending has been reconsidered and



still deemed to lack specificity regarding intensity data for different polymers per se to overcome this rejection.

### PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57-155 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Williams et al. [DNA 4(3):255(1985)].

It is noted that instant claim 102 lacks any limitation directed to limiting the area of any localized areas on a scanned substrate but does require the collection of intensity data from less than  $\frac{1}{2}$  of each of the localized areas on said substrate as well as intensity averaging over a localized region on the substrate. As previously described, Williams et al. discloses a computer implemented method practice of scanning dot blots as summarized in the title and abstract. Williams et al. discloses the array practice wherein nucleic acids, given as RNA (instant claim 103), are immobilized onto a nylon sheet followed by radioactive DNA probe hybridization which discloses the presence of target molecules already applied to the array as required in the above maintained specie election requirement. The computerized process of Williams et al. digitizes each spot or localized region as depicted in Figure 2 for an example spot with numerous pixels shown. Each of these pixels is clearly less than  $\frac{1}{2}$  of the spot area thus anticipating this instant claim limitation. Williams et al. also discloses the averaging

of spot intensity via pixel averaging on page 261, second column, first full paragraph, approximately  $\frac{3}{4}$  through the paragraph as required in the last 2 lines of instant claim 102.

The above averaging of pixel data over a localized area also anticipates the averaging limitation in other instant claims, such as claim 57. The spot areas of Williams et al. are larger than the 250,000 square micron areas of instant claim 57, however, the pixel areas are smaller as disclosed in the reference on page 257 in Figure 2 where each pixel is 200 X 200 microns which equals 40,000 square microns. One reasonable interpretation of instant claim 57 is that the areas which are averaged over is a given localized area as in the last two lines of instant claim 57 which is a pixel area which then gives average pixel intensity as disclosed in the reference as noted above on page 261, second column, etc. It is noted that the last 2 lines of instant claim 57 directs the averaging to a "given" localized area which may be interpreted either as one of the areas having an area smaller than 250,000 square microns or another area which is a given spot where the "given" limitation in instant claim 57 does not require that it be one of the localized areas with of polymer localization in lines 4-6 of instant claim 57. Under either of these interpretations instant claim 57 is anticipated. This anticipation includes supporting this rejection based on previous citations in Williams et al. and the above interpretations of the instant claim language also for independent claims 57 as well as 65, 73, 78, 86, 94, 102, 108, 120, 132, and 144 as well as dependent claims thereto as the claims are still not deemed to distinguish the scanner

practice per se from a scanner that scans any material as is doable with the scanner practice of the reference.

It is also lastly noted that the instant claims cite the limitation of "different" polymers, such as in line 4 of instant claim 57, but not that these polymers have a different sequence.

Therefore the above listed instant claims are anticipated by Williams et al.

### INFORMALITIES

The disclosure is objected to because of the following informalities:

It is noted that the Figure designations of parts thereof all contain capital letters for said parts. See, for example, Figure 9A and 9B. In conflict, references to the Figures in the specification utilize uncapitalized letters, such as 9a and 9b, on page 31, Examples 4 and 5, of the specification. Applicants are requested to review the entirety of the specification to correct these conflicts in referencing.

On page 20, line 37, a microfiche Appendix A is cited but without it being supplied to be included with the instant application.

On page 55, line 12, an Appendix B is cited but without said Appendix being filed with the instant application or thereafter.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

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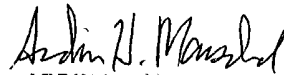
(November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).  
The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 7, 2004

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER